
















Structured Product Labeling (SPL) OTC Sub-team Teleconference

September 14, 2015, 1:00 – 2:00 pm ET

Summary Notes

I. Call Attendees by Company (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or alternatively you are listed and were not on the call) should notify Marcia Howard (mhoward@chpa.org).

-  Allergan
-  CareFusion
-  Chattem/Sanofi
-  Church & Dwight
-  CSC
-  FDA (invited speaker)
-  GSK
-  i4i
-  McNeil Consumer Healthcare/Johnson & Johnson
-  Perrigo
-  Pfizer Consumer Healthcare
-  Procter & Gamble
-  Purdue Pharma
-  Teva
-  CHPA staff (sub-team liaison)

II. Standing Teleconferences:

- Agreed to leave standing quarterly calls frequency and timing in place with teleconferences cancelled as needed.
- A new calendar invitation will be sent for the 2016 calls.
- SPL OTC subteam members will continue to receive real-time information via email. Specific issues or concerns requiring immediate assistance should be sent to Marcia Howard separately (mhoward@chpa.org).
- SPL OTC subteam members are encouraged to join and/or participate in the [Process ER/DL subteam](#) which addresses SPL issues across all product categories subject to electronic submissions.

III. Discussion

A. 2015 NLM SPL Jamboree Workshop

- September 23 (7:00 pm ET until): SPL Networking meeting (open to all attendees)
 - Bethesda [Rock Bottom](#) (Phillips Room)
7900 folk Avenue

Bethesda, MD 20814
301-652-1311

- Four blocks from Doubletree
<https://www.google.com/maps/place/Rock+Bottom+Restaurant+%26+Brewery/@38.9899612,-77.0973408,16.05z/data=!4m2!3m1!1s0x0:0xf01b2544bb142f71>
- September 24: NLM SPL Jamboree Workshop
 - In-person and webcast participation available.
 - Please review this web page for more details, including the workshop's agenda and registration:
http://www.nlm.nih.gov/mesh/spl_workshop_2015.html

B. Proper Document Types for OTC SPL Files

- Lonnie Smith (FDA) – invited speaker (*note summary notes are not intended to reflect exact quotation*)
 - SPL database is being used by a variety of downstream users including FDA staff which is positive.
 - During an internal FDA project using the SPL database, some OTC drug product listings reviewed were thought to contain an incorrect document type. Fortunately, relatively few errors (compared to the total number of submissions) have been found.
 - As with other aspects of electronic submissions, the accuracy of the SPL data is important given its many uses and the different users of the database.
 - To facilitate review and any necessary correction of these errors, FDA will provide Marcia Howard with documentation that can be shared with the full subteam. Companies can then use the set IDs to check the files on DailyMed for accuracy.
 - Alternately, companies can search DailyMed based on NDC Labeler codes and review each listing.
 - Companies should contact FDA if there is a question about the accuracy of the document type listed in the file.
 - For Rx-to-OTC switch products, if approval is granted after the first SPL file has been submitted, the sponsor should update the document type using the same set ID (rather than creating a new file). The sponsor can contact FDA to request a review and override once the switch can be confirmed.

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